



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2013-0029]

Availability of FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration through Labeling

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and opportunity for comment.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of guidance on allergens and other ingredients of public health concern that provides recommendations for identifying hazards when conducting a hazard analysis and to prevent and control hazards through hazard analysis and critical control point (HACCP) plans or Sanitation standard operating procedures (SOPs) or other prerequisite programs with respect to these substances. The emphasis of the guidelines is on meat and poultry products. The guidelines represent the best practice recommendations of FSIS, based on scientific and practical considerations. By following these guidelines, establishments are likely to ensure that product labels declare all ingredients, as required in the regulations, and that the product does not contain undeclared allergens or

other undeclared ingredients.

DATES: The Agency must receive comments by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: A downloadable version of the compliance guide is available to view and print at

[http://www.fsis.usda.gov/Regulations & Policies/Compliance Guides_Index/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/Compliance%20Guides/Index/index.asp). No hard copies of the compliance guide have been published.

FSIS invites interested persons to submit comments on this notice. Comments may be submitted by either of the following methods:

Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov/>. Follow the on-line instructions at that site for submitting comments.

Mail, including CD-ROMs: Send to Docket Room Manager, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163B, Washington, DC 20250-3700.

Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163B, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2013-0029. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or to comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E. Street SW, Room 8-164, Washington, DC 20250-3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495, or by Fax: (202) 720-2025.

SUPPLEMENTARY INFORMATION:

Under the Acts, meat and poultry products that contain an allergen that is not declared on the product label are adulterated because, to individuals who are allergic to the allergen, the products bear or contain a poisonous or deleterious substance (21 U.S.C. 453(g)(1) and 601(m)(1)). Also under the Acts, meat and poultry products are misbranded if the labeling on the products is false or misleading in any particular (21 U.S.C. 601 (n) (1) and 453(h) (1)). To prevent meat and poultry products from being misbranded, FSIS

regulations require a listing of all ingredients on the labels of products (9 CFR 317.2(f)(1) and 381.118(a)(1)).

In recent years (2008-2012), there has been a sustained increase in the number of recalls of FSIS-regulated products that contained undeclared allergens. These recalls are preventable, as many have been due to ingredient changes, product changes, products in the wrong package, or products with misprinted labels. The Agency is issuing these guidelines to provide meat and poultry establishments with recommendations on how to identify hazards with respect to allergens and other ingredients of public health concern when conducting their hazard analysis, prevent and control these hazards through HACCP plans, Sanitation SOPs, or other prerequisite programs, and properly declare allergens in product. These guidelines also provide information on proper procedures for processing, handling, storing, and labeling a product with an allergenic ingredient or ingredient of public health concern. Although the guidelines set out recommendations rather than requirements, FSIS encourages establishments to follow this guidance. The guidelines represent FSIS's thinking, and FSIS will update it as necessary to reflect comments received any additional information that becomes available.

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Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/federal-register>.

FSIS will also make copies of this Federal Register publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or

would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at

<http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service>. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Done at Washington, DC on: April 1, 2014.

Alfred V. Almanza,
Administrator.

[FR Doc. 2014-08956 Filed 04/18/2014 at 8:45 am; Publication Date: 04/21/2014]